NUREG-1556, Volume 12, Revision 1 - External Comments				
Comment No.	**Commenter**	**Location in the Volume**	**Comment**	**Resolution**
1	Virginia	General	Recommend adding verbiage to the Part 37 discussion boxes that these items will either be reviewed during a pre-licensing visit or during inspections.	Comment accepted. See new language on boxes indicating that security plans are not submitted to the NRC but may be subject to review and inspection.
2	Karl Von Ahn	Page 8-14, Section 8.6, Lines 10-11	In the "Response from applicant" portion of this section states that the applicant/ licensee needs to identify the sealed source and device (SSD) registration certificate number of each sealed source that the licensee wants to use or incorporate into a device. In terms of use, this goes beyond what is required in rule 10 CFR 30.32(g)(1) which only requires that the license submit the manufacturer and model number of the sealed source as registered or provide the equivalent information. Also, 10 CFR 30.32(g)(3) makes allowance for submitting only the manufacturer and model number of certain sources since they are not required to be registered under 10 CFR 32.210(g)(1) and do not have an SSD registration certificate. 10 CFR 30.32(g)(2) provides instructions for cases where the sealed source or device is not registered. Also, 10 CFR 30.32(g)(4) provides for allowances when it may not be feasible to submit all the manufacturer and model number information in the application. As a device manufacturer or distributor, the inclusion of a sealed source into a device would be covered under the device registration. The sealed source may either be a separately registered sealed source, or may have the source evaluation be included in the device registration. In the latter case, the manufacturer and model number of the sealed source may be known and a registration certificate may not exist.	Comment Accepted. Additional information added to section 8.6.

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			Therefore, I believe that the statement in lines 10-11 stating that the license must submit in a license application the SSD registration number for each sealed source or device is not backed up by rule and should be redacted.	
3	Karl Von Ahn	Page 8-42, Section 8.10.6, Lines 17-35	Subsection General Safety and Manufacturing Process Procedures, should include reminders that the manufacture and distribution of sealed sources and devices (SSDs) must be either (1) in accordance with the SSD registration and the quality assurance/quality control (QA/QC) procedures incorporated by reference in the SSD registration or (2) as indicated in their license submission for non-SSD registered sources and devices. The manufacturing process procedures should ensure that this is done. NUREG 1556 Volume 3 "Applications for Sealed Source and Device Evaluation and Registration" provides for the manufacturers and distributors of sealed sources and devices to provide information on the safety and construction of the products. The manufacture and distribution of these products are performed by licensees covered under this NUREG. It would appropriate to remind these manufacturers and distributors that their general safety and manufacturing process procedures should include the commitments made during the product registration process, or if applicable, the manufacturing license commitments for unregistered products. The only mention with regards to the SSD is in Appendix S for Medical Distribution, which is drawn from NUREG 1556 Volume 13 and is primarily for commercial radiopharmacy licenses.	Comment Accepted – Changes made to section 8.10.6, Page 8-45, lines 5-10
4	Virginia	Page 8-53, Section 8.10.10	Recommend adding a note to the Part 37 discussion box that the security requirements are not required to be submitted to the NRC for review and approval.	Comment partially accepted. See new language on boxes indicating that security plans are not

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				submitted to the NRC but may be subject to review and inspection.
5	Virginia	Page 8-57, Section 8.11	Move Figure 8-13 into the “release into air and water” section.	Comment Accepted: Figure moved to proper section.
6	Virginia	Page A-1	RG 8.10 is on revision 2, dated August 2016.	Comment Not Accepted: Appendix removed to make standard with1556 series.
7	Virginia	Page A-2	Missing reference to NUREG-1556 Vol 3, 7, 9, 11 and 13.	Comment Not Accepted: Appendix removed to make standard with1556 series.
8	Karl Von Ahn	Appendix H – Sample Audit Program	Within the sample audit program listed, there is no mention of licensee auditing their sealed source and device (SSD) program with respect to the manufacture and distribution of the products. NUREG 1556 Volume 3 “Applications for Sealed Source and Device Evaluation and Registration” provides for the manufacturers and distributors of sealed sources and devices to provide information on the safety and construction of the products. The manufacture and distribution of these products are performed by licensees covered under this NUREG. Therefore, it would be appropriate to provide licensees sample self-audits of their SSD program under this appendix. Considering the scope of each individual SSD registration, there could be a separate sample audit for an SSD registration (or	Comment Accepted, Appendix H revised to include comments

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			unregistered product) instead of just being inserted into the existing checklist. High level topics (audit points) for each SSD registration, or unregistered product model, audit could include: - Are the referenced SSD documents present and available? - Are the listed product model numbers distributed on the registration current? - Are the products manufactured in accordance with the SSD? - Have any changes been made to the engineering drawings, design features, or materials of construction? If so, was the SSD issuing agency notified of these changes? - Has the appropriate QA/QC audit checks been performed in accordance with the SSD registration application/references? - Are the products currently being manufactured and distributed? - For discontinued product lines, has an application for inactivation been made in accordance with 10 CFR 32.211? - Are applicable GL distribution reports made to the regulatory agencies? - Are the applicable regulatory documents (including disposal cost estimates) distributed with generally licensed devices current? [For example, see 10 CFR 32.51a] - For unregistered products, are they manufactured and distributed in accordance with the license submissions?	
9	Karl Von Ahn	Page H-6, Line 11	Line includes a reference to a “revised” 10 CFR Part 20. However the topics under the audit do not appear to be new. Should “revised” be deleted?	Comment Accepted: “Revised” is removed
10	Karl Von Ahn	Page H-6, Line 16	Line includes a reference to the “new” NRC Forms 4 and 5. Are these forms still “new” and should “new” be deleted?	Comment Accepted, “new “ is removed
11	Karl Von Ahn	Page H-6, Line 17	Line contain a typo, “10 CFR 20.502” should be “10 CFR 20.1502”	Comment Accepted,

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				Changed to 10 CFR 20.1502.